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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,157	03/09/2004	Martin Oft	DX06022 US 01	4687

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EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/797,157	OFT ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Currently, claims 1-18 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 in part, 3, 4 and 5 in part, 6, 7, 8 in part, 13 and 14, drawn to a method of modulating tumor growth, or treating cancer with an agonist of IL-23, wherein the agonist comprises an antibody, classified in class 424, subclass 130.1.

II. Claims 1 in part, 3, 4 and 5 in part, 7, 8 in part, 13 and 14, drawn to a method of modulating tumor growth, or treating cancer with an agonist of IL-23, wherein the agonist comprises a small molecule, classification depending upon the chemical entity of the small molecule.

III. Claims 1 in part, 3, 4 and 5 in part, 7, 8 in part, 13 and 14, drawn to a method of modulating tumor growth, or treating cancer with an agonist of IL-23, wherein the agonist comprises an anti-sense nucleic acid, classified in class 514, subclass 44.

IV. Claims 1 in part, 3, 4 and 5 in part, 7, 8 in part, 13 and 14, drawn to a method of modulating tumor growth, or treating cancer with an agonist of IL-23, wherein the agonist comprises a detectable label, classification depending upon the chemical entity of the agonist.

V. Claims 1 in part, 2, 3, 4 and 5 in part, 6, 7, 8 in part, 9, 10, 11 in part, and 12-14, drawn to a method of modulating tumor growth, or treating cancer with an antagonist of IL-23, wherein the antagonist comprises an antibody, classified in class 424, subclass 130.1.

VI. Claims 1 in part, 2, 3, 4 and 5 in part, 7, 8 in part, 9, 10, 11 in part, 13 and 14, drawn to a method of modulating tumor growth, or treating cancer with an antagonist of IL-23, wherein the antagonist comprises an extracellular region of IL-23R, classified in class 514, subclass 2.

VII. Claims 1 in part, 2, 3, 4 and 5 in part, 7, 8 in part, 9, 10, 11 in part, 13 and 14, drawn to a method of modulating tumor growth, or treating cancer with an antagonist of IL-23, wherein the antagonist comprises a small molecule, classification depending upon the chemical entity of the small molecule.

VIII. Claims 1 in part, 2, 3, 4 and 5 in part, 7, 8 in part, 9, 10, 11 in part, 13 and 14, drawn to a method of modulating tumor growth, or treating cancer with an antagonist of IL-23, wherein the antagonist comprises an anti-sense nucleic acid, classified in class 514, subclass 44.

IX. Claims 1 in part, 2, 3, 4 and 5 in part, 7, 8 in part, 9, 10, 11 in part, 13 and 14, drawn to a method of modulating tumor growth, or treating cancer with an antagonist of IL-23, wherein the antagonist comprises a detectable label, classification depending upon the chemical entity of the antagonist.

X. Claims 15 and 17 in part, and 18, drawn to a method of diagnosis of a cancer with a binding compound specifically binding a polypeptide, and a kit for the diagnosis comprising the binding compound antibody, classified in class 435, subclass 7.1.

XI. Claims 15 in part, 16, and 17 in part, drawn to a method of diagnosis of a cancer with a binding compound specifically binding a nucleic acid, and a kit for the diagnosis comprising the binding compound, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Although inventions I-IV are directed to a method of modulating tumor growth, or treating cancer with an agonist of IL-23, each method requires a different active ingredient with distinct chemical structure and functional property unrelated each from each other. Thus burdensome and non-coextensive searches are required.

Although inventions V-IX are directed to a method of modulating tumor growth, or treating cancer with an antagonist of IL-23, each method requires a different active ingredient with distinct chemical structure and functional property unrelated each from each other. Thus burdensome and non-coextensive searches are required.

Inventions I-IV and V-IX are directed to related processes, a method of modulating tumor growth, or treating cancer. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants;

and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Inventions I-IV use an agonist of IL-23, whereas Inventions V-IX use an antagonist of IL-23. Thus, they are mutually exclusive, are not capable of use together, and certainly are not obvious variants.

Inventions I-IX are unrelated to Inventions X and XI because they have different process steps and different starting and ending points, involve different subjects, and are for different purposes, such that they require separate searches.

Invention X is distinct from and unrelated to Invention XI, wherein the method of Invention X is for the detection of a polypeptide, whereas the method of Invention XI is for the detection of a nucleic acid, and thus, the test object, active ingredient, method steps, and outcome in each method are distinct from each other, and can not be used in the other method. Therefore, non-coextensive searches are required.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

2. Furthermore, regardless of which Invention applicants elect above, further **restriction** is required under 35 U.S.C. 121:

A. Elect one specific nucleotide or polypeptide sequence with SEQ ID NO from the following: SEQ ID NO:1-6, as applicable.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs is a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of the invention from Groups I-XI, and an election of the invention from Group A, to be examined even though the requirement be traversed (37 CFR 1.143), and (ii) identification of the claims encompassing the elected invention. Applicant is advised that neither I-XI nor A is species election requirement; rather, each of I-XI and A is a restriction requirement.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on 9:30 am - 7:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dong Jiang

Dong Jiang, Ph.D.
Patent Examiner
AU1646
3/16/06